NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANDOZ, INC. and RAREGEN, LLC, Plaintiffs, v. UNITED THERAPEUTICS, CORP. and SMITHS MEDICAL ASD, INC., Defendants.	Case No. 3:19-cv-10170-BRM-LHG **OPINION**

MARTINOTTI, DISTRICT JUDGE

Before this Court is Plaintiffs Sandoz Inc. ("Sandoz") and RareGen LLC's ("RareGen") (collectively, "Plaintiffs") Motion for a Preliminary Injunction pursuant to Fed. R. Civ. P. 65(a) and Local Civ. R. 65.1 to enjoin Defendants United Therapeutics Corp., ("UTC") and Smiths Medical ASD Inc., ("Smiths Medical") (collectively, "Defendants") from prohibiting specialty pharmacies from dispensing the CADD-MS® 3 pump and the cartridges used for that pump to persons other than users of UTC's Remodulin®. (ECF No. 106.) Defendants oppose the Motion. (ECF No. 122.) Also before the Court is UTC and Smiths Medical's Motion to Dismiss the Complaint for failure to state a claim for which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6). Plaintiffs oppose that Motion. (ECF No. 56.) Defendants filed a Reply. (ECF No. 59.) Having reviewed the parties' submissions filed in connection with the motions and having heard oral argument pursuant to Federal Rule of Civil Procedure 78(b) on December 10, 2019 (ECF No. 162), for the reasons set forth below and for good cause having been shown, Plaintiffs' Motion for a Preliminary Injunction is **DENIED**, while Defendants' Motion to Dismiss also is **DENIED**.

I. FACTUAL AND PROCEDURAL BACKGROUND[1]

This lawsuit concerns the sale of a brand name and a generic version of treprostinil, which is used to treat patients diagnosed with pulmonary arterial hypertension, or PAH. The branded drug, Remodulin®, is sold by UTC. Sandoz makes generic treprostinil.

A. Factual History

UTC makes Remodulin®, a drug approved in 2002 by the Food and Drug Administration ("FDA") for administration by, among other ways, injection, either subcutaneously, meaning under the skin, or intravenously directly into a patient's veins. (Compl. (ECF No. 1) ¶ 23.) Remodulin® is a branded version of treprostinil that is used to treat severe cases of pulmonary arterial hypertension ("PAH"). "PAH is a life-threatening disease that causes high blood pressure in the arteries that run from the heart to the lungs." (*Id.* at ¶ 2.) Injections of treprostinil are the general treatment for severe cases of PAH because "it is 'necessary to keep a continuous level of our key molecule, treprostinil, flushing through their pulmonary arteries 24/7. The only demonstrated way to achieve this continuously with an absolutely constant level of treprostinil levels is through a parenteral delivery system.'" (*Id.* at ¶ 18 (*quoting* UTC's Chief Executive).) More than half of Remodulin® patients receive subcutaneous injections of the drug. (*Id.* at ¶ 19.) This method is preferred because of a higher rate of infections among those receiving intravenous injections and its ease of use. (*See* Pls. Br. (ECF No. 106-1) at 4.) Subcutaneous administration requires a pump, such as the CADD-MS® 3 pump made by Smiths Medical. (ECF No. 1 at ¶ 20.) This pump "maintains a steady flow of medication into the patient's body and remains constantly in use, 24 hours a day, seven days a week." (*Id.* at ¶ 20.) The drug is placed in a cartridge that is

[1] Unless otherwise noted, the following facts are taken from Plaintiff's Complaint and assumed true for purposes of this Opinion. Pursuant to a Stipulated Scheduling Order, the parties engaged in limited discovery for the purposes of the preliminary injunction motion. (ECF No. 49.)

then placed in the pump. (*Id.*) Cartridges must be replaced every few days. (*Id.*) There are no other medical devices in use in the U.S. for these under-the-skin injections of treprostinil. (*Id.* at ¶ 21.)

Remodulin® had the market to itself until Sandoz introduced a generic version of treprostinil in the United States in March 2019. In 2011, Sandoz submitted an abbreviated new drug application, or an ANDA, for its generic version of treprostinil to the FDA. (*Id.* at ¶ 34.) Shortly thereafter, UTC sued Sandoz, contending the generic version infringed on its patent. (*Id.* at ¶ 36.) The parties ultimately settled that litigation in 2015. (*Id.* at ¶ 37.) Under the settlement agreement, Sandoz could begin marketing its generic version in June 2018. (*Id.* at ¶ 37.) For six months after its launch, it would be the maker of the only generic version of treprostinil. The settlement agreement disclaimed any right to a delivery device. (ECF No. 122 at 10 (citing Ex. 1006 § 13(c) ("Nothing in this agreement shall be construed to grant any right to any Third Party proprietary technology," including any "pump or delivery system"); Ex. 1069 (Sandoz: "Settlement agreement with UT does not mention pump/delivery.")).)

The CADD-MS® 3 pump is a modified insulin pump. (Pls. Br. (ECF No. 122) at 4.) Essentially, Smiths Medical reprogrammed the pump's software so the pump would dispense medicine by milliliters instead of "units of insulin." (ECF No. 122 at 4.) The pump debuted in 2006.[2] In 2014, Smiths Medical decided to discontinue making the pump because it was "increasingly expensive" to make and it was running out of FDA-cleared parts. (ECF No. 122 at 4 (citing Ex. 1079).) Smiths Medical informed UTC of its decision. (ECF No. 122 at 4.)

[2] Prior to the introduction of the CADD-MS® 3 in 2006, patients used the MiniMed Paradigm, a pump no longer used in the U.S. but still in use overseas. (ECF No. 162 at 39:15-16.) At oral argument, Defendants contended this pump could be cleared again for use in the United States. (*Id.* at 39:16-20.)

UTC was developing new ways of administering the drug, including an implantable pump and one using "acoustic volume sensing technology," but those alternatives were not ready for the market. (ECF No. 122 at 4 (citing Ex. 402).) UTC realized it could "not afford any gaps in supplying their $300M business to life-critical patients." (ECF No. 122 at 5 (citing Ex. 402).) Smiths Medical "circulated end-of-life notices to customers in August 2015," (ECF No. 122 at 5 (citing Donovan Dep. 328:15–331:5; Ex. 461)) and the manufacturing line was closed in October 2015. Smiths Medical's end-of-life notices "explained that the pump was discontinued 'effective immediately' and cartridges would be supplied for a limited duration." (ECF No. 122 at 5 (citing Ex. 1082).)[3]

Seeking to ensure supplies of pumps and cartridges until its delivery systems were ready for the market, UTC discussed with Smiths Medical ways to restart production of the CADD-MS® 3 pumps and cartridges. (ECF No. 122 at 5.)

In March 2016, UTC agreed to pay nearly [redacted] million for Smiths Medical to make [redacted] pumps and [redacted] cartridges. (ECF No. 122 at 6 (citing Declaration of Edward C. Bainbridge (ECF No. 131) ¶ 13, Ex. 67 (ECF No. 131-11) ("CADD MS® 3 Supply Agreement") §§ 3-7).) The Parties dispute whether that contract limited those products for sale to UTC or to customers that UTC approved. (*Compare* ECF No. 106-1 at 8 (citing Ex. 206 (ECF No. 131-22) at 3[4]; (Decl.

[3] The end-of-life notice stated, "Smiths Medical is continuing to supply the 3mL medication cartridge, 21-7450, to be available for the CADD-MS® 3 pump, for at least three years." (Bainbridge Decl. (ECF No. 133-4) ¶ 106, Ex. 1082 at 2).) The announcement also stated the company had no "direct replacement" for this pump, but that one potential replacement for some therapies was its CADD-Legacy® ambulatory infusion pumps. (*Id.*) Finally, the announcement stated, "Patients with pulmonary arterial hypertension (PAH) taking Remodulin® should contact their specialty pharmacy." (*Id.*)

[4] Email from Beth Rhodes, Vice President of Global Supply Chain and Alliance Management for UTC, stating UTC "would like to alter the terms of the cartridge supply arrangement so that it 'mirrors' the deal with respect to pumps." (ECF No. 131-22 at 3.)

of Ethan Glass (ECF No. 112) at ¶ 55, Dep. of Nathan Walker at 163:20-25[5])) and ECF No. 122 at 6 (citing Decl. of Michael Ian Benkowitz, president and chief operating officer of UTC, (ECF No. 129) ¶ 7)[6].) Under this Pump Supply Agreement, UTC agreed to pay [redacted] million immediately, and a total of [redacted] million for the pumps and [redacted] million for the cartridges. (ECF No. 122 at 6 (citing ECF No. 131-11, Ex. 67 §§ 3–6 & Ex. A).) This agreement allowed Smiths Medical to accept other offers to produce additional pumps or cartridges, though UTC had the right to match any offer. (*Id.* at 6 (citing ECF No. 131-11, Ex. 67 § 9).) Also, Smiths Medical was allowed to sell [redacted] "residual" pumps to its legacy customers. (ECF No. 122 at 6 (citing ECF No. 131 ¶¶ 13, 94, ECF No. 131-11 Ex. 67 § 5(a), ECF No. 132-42, Ex. 1070 ("First Amendment to CADD MS® 3 Supply Agreement")).)

On May 17, 2016, Sandoz's launch leaders learned from Smiths Medical's Senior Director of Device Development, Yaping Zhu, that the CADD-MS® 3 had been discontinued and that Smiths Medical was "not selling the pump anymore because they don't have any parts available to manufacture the pump." (ECF No. 122 at 12 (citing ECF No. 131-1, Ex. 5).)

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[5] Deposition of Nathan Walker, Global Product Manager at Smiths Medical:

> Q: And United Therapeutics agreed to acquire [redacted] cartridges, correct?
> . . .
> A: Correct. With an additional clause that they would purchase whatever remained after that.

(ECF No. 137-24 at 163:20-25.)

[6] "UTC would not have entered the 2016 CADD-MS 3 Supply Agreement and the 2017 Amendment without the restrictive covenants embodied in those agreements (which were carried through to the 2019 Agreements with the specialty pharmacies." (ECF No. 129 at ¶ 7.)

Later, Smiths Medical noticed that cartridges were being used at a faster rate than it projected. (ECF No. 122 at 6-7 (citing Decl. of Beth Rhodes, Vice President of Global Supply Chain and Alliance Management for UTC (ECF No. 126) ¶ 7).) Smiths Medical was able to find more materials to increase cartridge production. (ECF No. 122 at 6-7 (citing ECF No. 131 ¶¶ 15-17, 59, Exs. 77, 78, 79, 408).) Smiths Medical told UTC of this increased production capability and the two companies in July 2017 amended the Pump Supply Agreement. (ECF No. 122 at 8 (citing ECF No. 131-20, Ex. 202 ("Second Amendment to CADD MS® 3 Supply Agreement")).) Under this Second Amendment, Smiths Medical would produce [redacted] additional cartridges, extending UTC's supply from six to as many as 10 years, or for the expected life of all the CADD-MS® 3 pumps. (ECF No. 122 at 7 (citing Exs. 205 ("Nathan 1/24/2017 Email"), 1072 ("Walker 1/3/2017 Email"); ECF No. 126 ¶ 12).) Under the deal, Smiths Medical was allowed to sell [redacted] cartridges a year for two years for non-Remodulin® uses to its legacy customers. (ECF No. 122 at 7 (citing ECF No. 126 ¶ 9).) This amended contract stated that in order to ensure continued supply of cartridges for Remodulin® use, Smiths Medical agreed to use "commercially reasonable efforts to amend its existing agreements" with specialty pharmacies to require the pharmacies to ensure the cartridges were used only for Remodulin®. (ECF No. 122 at 8 (citing Ex. 208; ECF No. 126 ¶ 8) *see also* ECF No. 131-20 § 1(f).) Finally, Smiths Medical would produce monthly reports tracking cartridge sales, based on Smiths Medical's conclusion that the faster-than-expected run rate on cartridges resulted in part from "purchases for drugs other than Remodulin®." (ECF No. 122 at 7 (citing Exs. 208, 1072; ECF No. 126 ¶¶ 8–9).) For example, Smiths Medical discovered one customer, Alere, bought more than 88,000 cartridges for an anti-nausea drug, while a CVS division bought other cartridges for an unclear use. (ECF No. 122 at 9 (citing Exs. 89 (ECF No. 131-17), 1074).)

By July 2017, UTC effectively owned all remaining pumps and arranged in late 2017 via a Second Agreement to sell those pumps directly to specialty pharmacies. (ECF No. 122 at 8 (citing Exs. 722, 724).) The Second Agreement further contemplated that when Smiths Medical exhausted its [redacted] cartridge allocation, UTC would "own all remaining cartridges." (ECF No. 122 at 8 (citing Exs. 206, 722, 724, ECF No. 126 ¶¶ 9, 15).)

The FDA approved Sandoz's generic version in November 2017 for both under-the-skin and intravenous injections. (*Id.* at ¶ 38.) At some point in 2017, Sandoz tried to find two CADD-MS® 3 pumps and cartridges to test its drug, but it was unable to obtain any. (ECF No. 122 at 12 (citing ECF No. 131 at ¶ 6, Ex. 20 (Zhu 2/24/2017 email [redacted]; Ex. 21 (Joanne Flynn 3/2/2017 email ([redacted].)

In January 2018, UTC sought an update from Smiths Medical on progress in amending Smiths Medical's agreements with the pharmacies that were selling the cartridges: CVS and Accredo. (ECF No. 122 at 8 (citing ECF No. 131 at ¶ 12, Ex. 58 (Rhodes Dep.).) Smiths Medical sent drafts of amended agreements to those pharmacies with the cartridge-exclusive language in February 2018. (ECF No. 122 at 9 (citing ECF No. 132 ¶¶ 62, 63, Exs. 464 (Dep. of Richard Donovan), 465 (Donovan Dep.)).)

In early 2018, Sandoz's launch team noted, [redacted] (ECF No. 122 at 13 (citing ECF No. 132 at ¶ 91, Ex. 1067 (Sandoz Exec. Teletha Brown 1/10/2018 email)).)

In August 2018, Sandoz partnered with RareGen to jointly market the generic version of treprostinil. (ECF No. 1 ¶ 45.)

In fall 2018, Smiths Medical was nearing the end of its allocation of cartridges and preparing to send notices it would be discontinuing cartridge sales. (ECF No. 122 at 9 (citing ECF No. 131 ¶¶ 18, 19, Exs. 88, 89 to Dep. of Ross Genchoff),; Decl. of Carl Stamp, former Senior Vice President of Global Marketing and Strategy at Smiths Medical (ECF No. 128) ¶ 31; ECF No. 126 ¶ 15).)

When Sandoz and RareGen sought to order CADD-MS® 3 cartridges from Smiths Medical's distributors, Defendants blocked those orders and told the distributors they could sell the cartridges only to Accredo and CVS Specialty and only for use with Remodulin®. (ECF No. 1 ¶ 48.)

On December 21, 2018, UTC learned Smiths Medical had not signed Remodulin®-exclusive cartridge deals with the specialty pharmacies. (ECF No. 122 at 9 (citing ECF No. 131 ¶ 19, Ex. 89; ECF No. 126 ¶ 17).) UTC also learned then that Sandoz was about to launch generic treprostinil. (ECF No. 122 at 9 (citing ECF No. 126 ¶ 18; ECF No. 129 ¶ 11).) Faced with the prospect that cartridges guaranteed for Remodulin® patients could be siphoned for other uses, including sudden large purchases, Smiths Medical agreed UTC could approve every cartridge sale as Smiths Medical neared its allocation end. (ECF No. 122 at 9 (citing ECF No. 126 ¶¶ 17–19; ECF No. 129 ¶ 12).)

In mid-January 2019, RareGen [redacted]. (ECF No. 122 at 10 (citing ECF No. 131 ¶ 10, Ex. 56 to Dep. of Beth Rhodes ("Third Amendment to CADD MS® 3 Supply Agreement") (ECF No. 131-8) at § 6(a); ECF No. 131 ¶ 40, Ex. 329 (ECF No. 131-38) to Dep. of RareGen Chief Executive Damian deGoa).) Filling this order would have exhausted Smiths Medical's entire stock of cartridges for months. (ECF No. 122 at 10 (citing ECF No. 131-

8 at § 6(a); ECF No. 131-38).) Filling this order also would have meant patients using Remodulin® would have no cartridges. (ECF No. 122 at 10 (citing ECF No. 131-8 at § 6(a); ECF No. 131-38).)

In January 2019, Smiths Medical offered to "license [RareGen] their design for the MS-3 cartridge so [RareGen] could go and make it on [its] own," which Sandoz said [redacted]" (ECF No. 122 at 17 (citing ECF No. 131-38, ECF No. 132 ¶ 78, Ex. 813 to Dep. of Robert Spina (ECF No. 132-26) ("Treprostinil Alignment Discussion").) Smiths Medical submitted a proposed license agreement with terms Plaintiffs requested on March 26, 2019. (ECF No. 122 at 17 (citing ECF No. 131 ¶¶ 43, 44 Exs. 337 and 338 to deGoa Dep (ECF Nos. 131-41, 131-42; Bainbridge Decl. (ECF No. 133) ¶ 108, Ex. 1084 (ECF No. 133-6) ("3-26-2019 Boyle email)).)

By April 2019, Smiths Medical had only [redacted] cartridges remaining. As UTC already had the right to direct the distribution of all of Smiths Medical's future stock, Smiths Medical agreed to streamline distribution by selling all units directly to UTC and allowing UTC to manage all sales functions. (ECF No. 122 at 10 (citing ECF No. 126 ¶¶ 22–23; Decl. of Kevin T. Gray, UTC Senior Vice President for Strategic Operations (ECF No. 130) ¶¶ 7–8).) This arrangement was accomplished through a Third Amendment dated April 8, 2019, after Sandoz launched treprostinil and eight days before Plaintiffs filed this action. (ECF No. 122 at 10 (citing ECF No. 131-8).)

Plaintiffs [redacted]. (ECF No. 122 at 17-18 (citing Aff. of RareGen Chief Executive Damian deGoa (ECF No. 108) ¶¶ 26–31; Exs. 372, 1061, 1062).)

Sandoz alleges UTC and Smiths Medical cornered the market for cartridges needed for under-the-skin injections of Remodulin® and generic treprostinil, effectively blocking the entry of Sandoz's generic product in the market and thus maintaining high prices for Remodulin®. (ECF

No. 1 ¶ 50.) This result was accomplished first by agreements between UTC and Smiths Medical under which UTC effectively bought all cartridges for the CADD-MS® 3 pump made by Smiths Medical and then by agreements between Smiths Medical and specialty pharmacies circumscribing the ability of those pharmacies to sell cartridges to any user other than Remodulin® patients.

B. Procedural History

On April 16, 2019, Sandoz filed a six-count Complaint against Defendants. (ECF No. 1.) The Complaint alleged restraint of trade pursuant to 15 U.S.C. § 1 (Count One), monopolization pursuant to § 2 (Count Two), two further counts of restraint of trade based on state law (N.J. Stat. Ann. § 56:9-3 for Count Three; N.C. Gen. Stat. § 75-1 for Count Four); Count Five's unfair trade practices based on North Carolina law (N.C. Gen. Stat. § 75-1.1); and Tortious Interference with prospective economic advantage (Count Six). (ECF No. 1 ¶¶ 78-103.) On April 19, 2019, Plaintiffs filed an application pursuant to L. Civ. R. 65.1 seeking expedited discovery. Discovery parameters were set by a May 8, 2019 Stipulated Scheduling Order. (ECF No. 49.) The Application terminated on August 9, 2019. (*See* Docket Entry for 9/2019.)

Defendants filed their Motion to Dismiss on May 24, 2019. (ECF No. 53). Plaintiffs filed their opposition to the Motion on June 17, 2019. (ECF No. 56.) Defendants filed their Reply on June 24, 2019. (ECF No. 59.)

Plaintiffs filed this Motion for a Preliminary Injunction on October 4, 2019. (ECF No. 106.) Defendants filed their opposition on October 25, 2019. (ECF No. 122.) As stated in their Brief in Support of the Motion for a Preliminary Injunction, Plaintiffs waived their right to file a Reply in order to obtain an expedited hearing on this Motion. (ECF No. 106 at 37.) Nonetheless, Plaintiffs filed supplemental evidence in support of the Motion on November 1, 2019. (ECF No. 137.)

On October 15, 2019, Defendants filed a Motion for Sanctions against Plaintiffs, alleging Plaintiffs "violated the Court's Stipulated Confidentiality Order [ECF No. 55] by publicly filing material in their Memorandum in Support of Plaintiffs' Motion for a Preliminary Injunction [ECF No. 106-1] they knew UTC and Smiths Medical had designated as "Highly Confidential" and "Confidential." That Motion is pending.

II. LEGAL STANDARD

A. Preliminary Injunction Standard

"Preliminary injunctive relief is an 'extraordinary remedy, which should be granted only in limited circumstances.'" *Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 210 (3d Cir. 2014) (*quoting Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3d Cir. 2002)). A plaintiff seeking a preliminary injunction must establish that he has 1) a reasonable probability of eventual success in the litigation, 2) that plaintiff will be irreparably injured if relief is not granted, 3) the possibility of harm to other interested persons from the grant or denial of an injunction, and 4) the public interest. *Reilly v. City of Harrisburg*, 858 F.3d 173, 176 (3d Cir. 2017) (citing *Del. River Port Auth. v. Transamerican Trailer Transport, Inc.*, 501 F. 2d 917, 919-20 (3d Cir. 1974 (citations omitted).)

The failure to establish any of the four elements "renders a preliminary injunction inappropriate." *Ferring*, 765 F.3d at 210 (*quoting NutraSweet Co. v. Vit-Mar Enters., Inc.*, 176 F.3d 151, 153 (3d Cir. 1999)). "The movant bears the burden of showing that these four factors weigh in favor of granting the injunction." *Ferring*, 765 F.3d at 210 (*citing Opticians Ass'n of Am. v. Indep. Opticians of Am.*, 920 F.2d 187, 192 (3d Cir. 1990).)

B. Rule 12(b)(6) Standard

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for misconduct alleged." *Id.* This "plausibility standard" requires that the complaint allege "more than a sheer possibility that a defendant has acted unlawfully," but it "is not akin to a probability requirement.'" *Id.* (quoting *Twombly*, 550 U.S. at 556). "Detailed factual allegations" are not required, but "more than an unadorned, the defendant-harmed-me accusation" must be pleaded; it must include "factual enhancements" and not just conclusory statements or a recitation of the elements of a cause of action. *Id.* (citing *Twombly*, 550 U.S. at 555, 557).

"Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)). However, courts are "not compelled to accept 'unsupported conclusions and unwarranted inferences,'" *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007) (quoting *Schuylkill Energy Res. Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997)), nor "a legal conclusion couched as a factual allegation." *Papasan*, 478 U.S. at 286.

While, as a general rule, the court may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to Rule 12(b)(6), the Third Circuit has held that "a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant to Rule 56]." *In re Rockefeller Ctr. Props. Sec.*

Litig., 184 F.3d 280, 287 (3d Cir. 1999). Specifically, courts may consider any "'document *integral to or explicitly relied upon* in the complaint.'" *Burlington Coat Factory*, 114 F.3d at 1426 (quoting *Shaw*, 82 F.3d at 1220).

III. DECISION

Plaintiffs seek a preliminary injunction based on their contention they "are likely to succeed on the merits of their federal antitrust claims under Section 1 and Section 2 of the Sherman Act, 15 U.S.C. §§ 1-2." (ECF No. 106.) The first prong of the *Reilly* test requires the Court to determine whether the moving party, here the Plaintiffs, has a reasonable probability of eventual success in the litigation.

To prevail on a § 1 claim, Plaintiffs must prove "(1) concerted action by the defendants; (2) that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted action was illegal; and (4) that the plaintiff was injured as a proximate result of the concerted action." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 442 (3d Cir. 1997) (citing *Mathews v. Lancaster General Hospital*, 87 F.3d 624, 639 (3d Cir. 1996); *Orson Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1366 (3d Cir. 1996); *Petruzzi's IGA Supermarkets, Inc. v. Darling–Delaware Co., Inc.*, 998 F.2d 1224, 1229 (3d Cir. 1993)).

To prevail on their § 2 allegation Plaintiffs must show Defendants (1) possess monopoly power in the relevant market and (2) have willfully maintained or acquired that power "as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 596 n.19, 105 S. Ct. 2847, 2854 n.19, 86 L. Ed. 2d 467 (1985) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71, 86 S. Ct. 1698, 1703–04, 16 L. Ed. 2d 778 (1966)).

Before embarking on that inquiry, however, there are three primary lenses through which a court examines antitrust claims. As the parties do not agree on the appropriate standard for inquiring into the challenged agreements, the Court must review these standards to determine which is appropriate to this Motion.

A. *Per Se* Rule

The *per se* rule treats certain categories of restraints as necessarily illegal. *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 127 S. Ct. 2705, 2713, 551 U.S. 877, 886 (2007) (citing *Business Electronics Corp. v. Sharp Electronics Corp.*, 485 U.S. 717, 723, 108 S. Ct. 1515, 99 L. Ed. 2d 808 (1988). The Supreme Court has recognized that *per se* unlawful restraints "include horizontal agreements among competitors to fix prices, or [] divide markets." *Id.* (internal punctuation and case cites omitted). "To justify a *per se* prohibition a restraint must have 'manifestly anticompetitive' effects, . . . and 'lack any redeeming virtue.'" *Id.* at 2713. In other words, the "*per se* illegality rule applies when a business practice 'on its face, has no purpose except stifling competition.'" *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 402 (3d Cir. 2016) (citing *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 221 (3d Cir. 2011) (quoting *Eichorn v. AT&T Corp.*, 248 F.3d 131, 143 (3d Cir. 2001)); *see, e.g., N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5, 78 S. Ct. 514, 2 L. Ed. 2d 545 (1958) ("Among the practices which the courts have heretofore deemed to be unlawful in and of themselves are price fixing, division of markets, group boycotts, and tying arrangements." (internal citations omitted)).) Neither party argues the *per se* standard applies, and this litigation involves none of the categories identified in the case law as subject to a *per se* analysis, such as agreements controlling prices, so the Court moves to the quick-look standard.

B. Quick Look

The quick-look analysis is reserved for allegedly anticompetitive behavior that does not come under the *per se* rule but is "so patently bad that even a brief glance at its impact, lack of business benefit and anticompetitive intent suffice to condemn it." *U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 594 (1st Cir. 1993). Plaintiffs argue "the evidence of anticompetitive effects here is so strong" the quick look approach is merited. The Court disagrees.

The agreements challenged by Sandoz do not directly relate to pricing, though Plaintiff says the effect of the agreements has kept prices in this arena higher than is to be expected when a generic version enters a market dominated by a brand-name drug. The challenged agreements also are not supply agreements as typically understood in antitrust parlance, meaning these agreements do not control the supply of the actual products made by UTC or Sandoz. Rather, the subject of the agreements is equipment needed to administer the drugs, which is produced by Smiths Medical and provided to patients by specialty pharmacies. Defendants cite *Ohio v. Am. Express Co.* for the proposition that the quick-look standard cannot apply "to § 1 claims premised upon vertical restraints like exclusive dealing." (ECF No. 122 at 24-25 n.7 (citing *Am. Express*, 138 S. Ct. 2274, 2285 n.7 (2018); *Eisai*, 821 F.3d at 403; *U.S. Healthcare*, 986 F.2d at 595 (noting that "no 'quick look' would ever suffice" for exclusive dealing claims, which require "the most careful weighing of alleged dangers and potential benefits").) The Court agrees, and therefore declines to adopt the quick-look approach for this Motion.

C. Rule of Reason

The rule of reason is the default for assessing the reasonableness of a restraint on competition. *See Texaco, Inc. v. Dagher*, 547 U.S. 1, 5 (2006). Under this rule, the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be

prohibited as imposing an unreasonable restraint on competition." *Leegin Creative Leather Products*, 127 S. Ct. at 2712 (citing *Continental T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49, 97 S. Ct. 2549, 53 L. Ed. 2d 568 (1977)). As the Third Circuit has stated:

> The plaintiff bears an initial burden under the rule of reason of showing that the alleged combination or agreement produced adverse, anti-competitive effects within the relevant product and geographic markets. The plaintiff may satisfy this burden by proving the existence of actual anticompetitive effects, such as reduction of output, increase in price, or deterioration in quality of goods or services. Such proof is often impossible to make, however, due to the difficulty of isolating the market effects of challenged conduct. Accordingly, courts typically allow proof of the defendant's market power instead. Market power, the ability to raise prices above those that would prevail in a competitive market, is essentially a surrogate for detrimental effects.

King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 412 (3d Cir. 2015)

If Plaintiffs make such a showing, the burden shifts to Defendants to offer evidence of the procompetitive effects of their agreement. *Id*. The burden then shifts back to Plaintiffs to prove any legitimate competitive benefits offered by defendants could have been achieved through less restrictive means. *Id*. Having determined the *per se* and quick-look approaches do not apply to these claims, the Court adopts the rule-of-reason standard for examining allegedly anticompetitive conduct under § 1 of the Sherman Antitrust Act.

Having determined the rule of reason applies, the Court begins with Plaintiffs' § 1 claim.

1. § 1 Antitrust Claims

Pursuant to the Sherman Antitrust Act, "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." 15 U.S.C. § 1. A literal reading suggests "every" contract, combination or otherwise that restrains trade is actionable, but the Supreme Court has made clear only unreasonable restraints are proscribed. *See Nat'l Collegiate Athletic Ass'n v. Bd. of Regents*

of the Univ. of Okla., 468 U.S. 85, 98 (1984). A plaintiff seeking a preliminary injunction must establish that he has 1) a reasonable probability of eventual success in the litigation, 2) that plaintiff will be irreparably injured if relief is not granted, 3) the possibility of harm to other interested persons from the grant or denial of an injunction, and 4) the public interest. *Reilly*, 858 F.3d at 176 (citing *Del. River Port Auth.*, 501 F. 2d at 919-20.)

a. Reasonable Probability of Eventual Success on the Litigation

To satisfy this first *Reilly* prong, a movant must "demonstrate that it can win on the merits[,] which requires a showing significantly better than negligible but not necessarily more likely than not." (*Id.*) (internal punctuation omitted) The Third Circuit does not require "a more-likely-than-not showing of success on the merits because a 'likelihood' [of success on the merits] does not mean more likely than not." *Id.* at 179 n.3 (quoting *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011) (en banc) (internal punctuation omitted); *cf. Nken v. Holder*, 556 U.S. 418, 434 (2009) ("It is not enough that the chance of success on the merits be better than negligible," and "more than a mere 'possibility' of relief is required.") (internal quotation marks omitted)).

Whether Plaintiffs are likely to succeed on the merits requires the Court to determine if Smiths Medical and UTC engaged in illegal, concerted action that produced an anticompetitive result that was the proximate cause of any injury to Plaintiffs. *Queen City Pizza*, 124 F.3d at 442. It is undisputed Smiths Medical and UTC acted in concert. Where the parties differ is in the onset of and motivations for that concerted action. Plaintiffs identify that concerted action as the Third Amendment signed in 2019 under which Smiths Medical expressly agreed to sell all cartridges directly to UTC, while Defendants say the Court should look instead to a 2016 Pump Supply Agreement between the two entities of which that Third Amendment is merely a prodigy. Either

agreement establishes that Plaintiffs can show action in concert by Defendants, as required by *Queen City Pizza*.

Plaintiffs then must show that this action in concert was illegal, meaning in the context of antitrust allegations and the parties engaged in anticompetitive conduct that produced an unreasonable restraint on trade, and that Sandoz suffered an antitrust injury as a result. *Eisai*, 821 F.3d at 402.

i. Anticompetitive Conduct

As the Supreme Court recently set out in *Ohio v. Am. Express, Co.*:

> To determine whether a restraint violates the rule of reason, the parties agree that a three-step, burden-shifting framework applies. Under this framework, the plaintiff has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market. If the plaintiff carries its burden, then the burden shifts to the defendant to show a procompetitive rationale for the restraint. If the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means.

138 S. Ct. at 2284 (internal citations omitted).

In other words, courts must "distinguis[h] between restraints with anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer's best interest." *Id.* (citing *Leegin Creative Leather Products*, 551 U.S. at 886, 127 S. Ct. 2705, 168 L. Ed. 2d 623). "Anticompetitive effect has been described as a reduction of output, increase in price, or deterioration in quality of goods and services." *Wallace v. Free Software Foundation, Inc.*, No. 1:05CV0618, 2005 WL 3239208, at *3 (S.D. Ind. Nov. 28, 2005) (citing *Generac Corp. v. Caterpillar Inc.*, 172 F.3d 971, 978 (7th Cir. 1999); *Wilk v. Am. Med. Ass'n*, 895 F.2d 352, 360-62 (7th Cir. 1990) (impeding consumers' free choice is an anticompetitive effect); *Les Shockley Racing, Inc. v. Nat'l Hot Rod Ass'n*, 884 F.2d 504, 508-09 (9th Cir. 1989) (finding that, in a market

that "is both narrow and discrete and the market participants are few," the loss of a competitor may result in an anticompetitive effect if there is an effect on price or availability, the allocation of resources, or opportunities for market entry). Plaintiffs have the burden of showing anticompetitive effects such as supracompetitive prices or reduced output or quality by either direct evidence or by indirect evidence—meaning by defining the relevant market, showing that defendants have a dominant share of that market, and showing the existence of significant entry and expansion barriers. *Theme Promotions, Inc. v. News Am. Mktg. FSI*, 539 F.3d 991, 1001 (9th Cir. 2008).

Plaintiffs claim direct evidence shows prices remain artificially inflated because the cartridge contracts between Defendants have prevented Sandoz from gaining traction in the market for under-the-skin injections of its generic drug. This result is apparent, Sandoz argues, from the fact that the average price per milligram of Remodulin® declined [redacted] in the quarter following the introduction of intravenously injected generic treprostinil,[7] while the weighted average price of Remodulin® has fallen only [redacted] in the subcutaneous market. Plaintiffs make no arguments regarding reduced output or quality. Defendants counter that prices have declined in inflation-adjusted terms in the past decade and the price of Remodulin® has declined since its 2002 launch.

[7] Plaintiffs state, "Specialty pharmacies pay [redacted] less for generic treprostinil than they do for Remodulin." (ECF No. 106-1 at 21 (citing Report of Plaintiffs' Expert Mohar Rao, Ph.D. (ECF No. 109) at ¶ 79).) Plaintiffs argue that, as a result, "the price for subcutaneously-administered treprostinil should have fallen to the same level as the price for intravenous treatments." (ECF No. 106-1 at 21.) However, the Rao Report also states that "the price of Remodulin was unaffected by the introduction of other branded PAH treatments and their generic equivalents." (*Id.* ¶ 80.) Rao concludes from this that UTC had monopoly power in the market before the introduction of Sandoz's treprostinil. But the Rao Report also quotes UTC Chief Executive Martine Rothblatt as saying in 2017 that Romodulin "remained the overwhelming market leader because physicians ask the payers to pay for the drug as prescribed. Payers who have long since seen the high cost of pulmonary hypertension patients when they become unstable, they too don't want to mess with what's working and prefer to pay for Remodulin." (*Id.* ¶ 81.) The Court concludes the dynamic described by Rothblatt may constitute a marketplace advantage accruing to UTC and supporting Remodulin prices that would not be anticompetitive.

The Court concludes the direct evidence relied on by Plaintiffs, that Remodulin® prices fell in the subcutaneous market but not by the [redacted] decline recorded for intravenously injected market, is too small a difference without further context to be dispositive. Therefore, the Court must look to indirect evidence to establish whether the market power of Defendants has anticompetitive effects. *Theme Promotions*, 539 F.3d at 1001.

The rule of reason requires courts to conduct a fact-specific assessment of "market power and market structure . . . to assess the [restraint]'s actual effect" on competition. *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768, 104 S. Ct. 2731, 81 L.Ed.2d 628 (1984). Plaintiffs contend the relevant market comprises only subcutaneously injected treprostinil in the U.S. (ECF No. 106-1 at 22-24). Furthermore, Sandoz contends the evidence of anticompetitive conduct is so strong it need only define the rough contours of the relevant market, pursuant to *Deborah Heart & Lung Ctr. v. Penn Presbyterian Med. Ctr.*, No. 11-1290, 2011 WL 6936276, at *7 (D.N.J. Dec. 30, 2011). For the indirect-evidence approach, Plaintiffs must define the relevant market, show that defendants have a dominant share of that market, and show the existence of significant entry and expansion barriers. *Theme Promotions*, 539 F.3d at 1001. The Court will look at each in turn.

ii. Relevant Market

As the Supreme Court stated in *American Express*:

> Courts usually cannot properly apply the rule of reason without an accurate definition of the relevant market. Without a definition of the market there is no way to measure [the defendant's] ability to lessen or destroy competition. Thus, the relevant market is defined as the area of effective competition. Typically this is the arena within which significant substitution in consumption or production occurs. But courts should combine different products or services into a single market when "that combination reflects commercial realities.

138 S. Ct. at 2285 (internal punctuation and citations omitted).

Sandoz contends the relevant market comprises only under-the-skin injections in the United States because patients who are prescribed such injections have no close alternatives. (ECF No. 106-1 at 23-24.) Sandoz argues this is shown in part by the very agreements it is challenging, which would make no economic sense if patients prescribed under-the-skin injections could simply transition to intravenous treatments. (*Id.* at 24.)

Defendants argue that because prices have declined for treprostinil and because Plaintiffs offer no evidence of any decline in output, Plaintiffs cannot assert any direct evidence of harm to competition. Therefore, Defendants claim, Plaintiffs must do more than define the rough contours of the relevant market. Defendants contend Plaintiffs cannot more precisely define the relevant market because the under-the-skin market "is a gerrymandered market that finds no support in the record." (ECF No. 122 at 37 (citing *Queen City Pizza*, 124 F.3d at 438 ("[N]o court has defined a relevant product market with reference to the particular contractual restraints of the plaintiff")).) Defendants further contend that even if the rough-contours analysis was valid, Plaintiffs' argument still fails because this class of drug has "overlapping indications and physicians prescribe them to all patient classes," as seen by the fact that "switching among Remodulin® and non-injected prostacyclins is prevalent." (*Id.* at 37 n.18 (citing Defs.' Expert Rpt. of Eric M. Gaier, Ph.D. (ECF No. 125) ¶¶ 175-84, Figs. 12-16).) Furthermore, Defendants contend there is "evidence of substantial switching between subcutaneous and intravenous uses—the clearest indication the two compete in the same market. (*Id.* at 37-38 (citing ECF No. 125) ¶ 170 & Fig. 11; Dep. of Defs.

Expert Aaron B. Waxman, M.D. (ECF No. 137-26) 127:13–16[8]; 141:10–20[9]).) Indeed, Defendants argue UTC "does not distinguish between subcutaneous and intravenous uses in sales or pricing." (*Id.* at 38 (citing Benkowitz 30(b)(6) Dep. (ECF No. 112-6) 14:20–15:3; Benkowitz Dep. (ECF No. 112-5) 54:24–55:11; Rhodes Dep. (ECF No. 137-17) 43:9–23).)

The Supreme Court has stated the "outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe Co. v. U.S.*, 370 U.S. 294, 325, 82 S. Ct. 1502, 1523, 8 L. Ed. 2d 510 (1962). It is obvious there was only one treprostinil substitute for Remodulin® at the time this action commenced, as it is undisputed the brand-name drug was the only such product on the market cleared by the FDA until it approved Sandoz's generic version in 2018. It also is undisputed that the settlement agreement between Sandoz and UTC provided a period of six months after the Sandoz launch during which Sandoz's treprostinil would be the only generic version on the market. Defendants argue there is cross-elasticity of demand between the

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[8] Dr. Waxman testified:

> Q: Have you ever had a patient that switched from intravenous treprostinil to subcutaneous treprostinil?
> A: We have, yes.

(ECF No. 137-26 at 127:13-16.)

[9] Dr. Waxman testified:

> Q: Your patients who participated in the subcutaneous treprostinil clinical trial, were those patients able to tolerate subcutaneous administration of treprostinil for the duration of the clinical trial?
> A: They tolerated it because they had no choice. But as soon as the trial was over, three immediately switched to epoprostenol. And then as soon as intravenous treprostinil became available, the rest switched over.

(ECF No. 137-26 at 141:10-20.)

subcutaneous and intravenous markets, though Plaintiffs point to testimony of Benkowitz, president and chief operating officer of UTC, who estimated the percentage of switchers "probably still wouldn't be much higher than single digits." (*See* Decl. of Ethan Glass (ECF No. 112) ¶ 109, Ex. E (ECF No. 112-5) 59:11-60:1).)

The Court observes that Plaintiffs' definition of the relevant market as including only the subcutaneously injected treprostinil market in the United States would be sufficient to survive a motion to dismiss. *F.T.C. v. Mylan Laboratories, Inc.*, 62 F. Supp. 2d 25, 54 (D.D.C. 1999) (citing *Daniel v. American Bd. of Emergency Medicine*, 802 F.Supp. 912, 925-26 (W.D.N.Y. 1992) ("The notice pleading system requires only that the allegations in the complaint give notice as to what markets are being brought into issue."); *Michael Anthony Jewelers v. Peacock Jewelry*, 795 F.Supp. 639, 647 (S.D.N.Y. 1992). However, the inquiry here is whether Plaintiffs have a reasonable probability of eventual success in the litigation. *Reilly*, 858 F.3d at 176. "[I]n most cases, proper market definition can be determined only after a factual inquiry into the commercial realities faced by consumers." *Queen City Pizza*, 124 F.3d at 436 (citing *Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, 482, 112 S. Ct. 2072, 2090, 119 L. Ed. 2d 265 (1992). While it is "entirely plausible that plaintiffs will prove a set of facts that supports" their definition of the relevant market at trial as being limited to subcutaneous injections in the U.S., *see Mylan Laboratories*, 62 F. Supp. 2d at 54, it is not clear on the limited facts before the Court that Plaintiffs have carried their burden.

However, the Court concludes the distinction between a relevant market defined as only subcutaneous injections or one that also includes intravenous injections is a distinction without a difference, as UTC's share of both those markets likely connotes market power. *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005) ("Absent other pertinent factors, a share

significantly larger than 55% has been required to established *prima facie* market power"); *see also Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 202 (3d Cir. 1992).)[10]

iii. Existence of Entry and Expansion Barriers

Certainly it is a commonplace that the marketplace for pharmaceutical treatments has significant entry and expansion barriers as contemplated by *Theme Promotions.*, 539 F.3d 1046, 1053 (9th Cir. 2008). The FDA approval-process alone is lengthy, laborious and expensive. *See Ethypharm S.A. France v. Abbott Laboratories*, 707 F.3d 223, 236 (3d Cir. 2013) ("The FDA carefully regulates the pharmaceutical industry and imposes stringent requirements on entities seeking to sell drugs in the United States." *See generally* 21 U.S.C. § 355 (describing requirements for NDA approvals); *id.* § 393 (establishing the FDA and providing its scope).

Plaintiffs have established that UTC has market power: it commands a dominant share of the markets for treprostinil administered via both the under the skin and intravenously, and this a marketplace with significant barriers both to entry and expansion. Having determined Plaintiff has showed by indirect evidence the market power of Defendants pursuant to *Theme Promotions*, the Court now turns to the question of whether the restraints complained of by Plaintiffs—that UTC moved to prevent cartridges being used in the administration of generic treprostinil by requiring Smiths Medical to amend its agreements with specialty pharmacies—resulted in an antitrust injury and whether Plaintiffs have established they have a reasonable probability of eventual success in evidencing an antitrust injury.

[10] Plaintiffs contend UTC's share of the subcutaneously administered treprostinil market is 100%. (ECF No. 106-1 at 28-29 (citing Rao Report, ECF No. 109, at Tab 12; Benkowitz Dep., ECF No. 112-5, at 55:23-56:2).) Plaintiffs contend UTC's share of the market for all injected prostacyclins is 60% to 80%. (*Id.* (citing ECF No. 112 ¶ 61, Ex. 251 to Dep. of Jay Watson at 3 ("Current parenteral prostacyclin share . . . Remodulin® market leader with ~80% share"); ECF No. 112 ¶ 138, Ex. 1014 at 350-51 ("We own about 82% share in the parental market."); ECF No. 112 ¶ 139, Ex. 1015 ¶ 879; ECF No. 112-5, at 54:13-18; ECF No. 109 ¶ 98 n.187).)

iv. Antitrust Injury

An antitrust injury means an injury "of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Ethypharm*, 707 F.3d at 233 (citing *Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc.*, 429 U.S. 477, 489, 97 S. Ct. 690, 50 L.Ed.2d 701 (1977)).

Plaintiffs claim an antitrust injury from being effectively blocked from the market for subcutaneous injections of treprostinil by the agreements they allege Defendants forced on specialty pharmacies limiting cartridge sales to Remodulin® patients. The Court concludes it is clear arrangements that prevent competitors from entering a market constitutes an antitrust injury as contemplated by *Ethypharm S.A. France*, in that creating such barriers is one of the actions antitrust laws were intended to combat. *See Eastman Kodak*, 112 S. Ct. at 2092, 504 U.S. at 485 ("one of the evils proscribed by the antitrust laws is the creation of entry barriers to potential competitors….").

Defendants contend Plaintiffs cannot show an antitrust injury because "they cannot show that 'but for' Defendants' conduct, Plaintiffs would have obtained cartridges for launch." (ECF No. 122 at 38 (citing *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 166 (3d Cir. 2017).) Defendants' position misreads the burden-shifting process laid out by *American Express*. *See Am. Express*, 138 S. Ct. at 2284. At stage one, Plaintiffs' burden is to establish that the challenged restraint, here the Third Amendment under which UTC has corralled the entire supply of cartridges, has a substantial anticompetitive effect, in this case, blocking Sandoz from reaching consumers with its generic version of treprostinil. *See id.* The Court concludes Plaintiffs have met that burden. The Court now must determine whether Defendants can demonstrate a procompetitive rationale for the restraint. *See id.* (setting forth step two).

Defendants argue there is no restraint because there would have been no cartridges on the market in 2018 without UTC's roughly [redacted] million[11] agreement with Smiths Medical to restart production because Smiths Medical was terminating the product.

Courts must "distinguis[h] between restraints with anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer's best interest." *Am. Express*, 138 S. Ct. at 2284. While Plaintiffs argue the 2019 agreements are *prima facie* evidence of anticompetitive conduct motivated by an illicit desire to block Sandoz from the marketplace,[12] Defendants argue the genesis of those 2019 agreements were contracts struck between Defendants in 2016 (the Pump Supply Agreement) and amended in 2017 (Second Amendment) and in 2019 (Third Amendment). Those agreements were struck, Defendants argue, not to keep Sandoz out of the market, because Sandoz had not yet launched its product, but rather to ensure a continued supply of a product, cartridges, for patients using Remodulin® that otherwise would have been discontinued by the manufacturer before Plaintiffs' launch. Also, Defendants

[11] Plaintiffs call the Pump Supply Agreement a "purchase guarantee," (ECF No. 106-1 at 33) while UTC calls it a capital expenditure and an investment. (ECF No. 122 at 4-6, 30 n.12). Either way, Defendants argue, Smiths Medical would not have agreed to restart production without the UTC funds. (*Id.* at 30 n.12 (citing Stamp Decl. (ECF No. 128) ¶¶ 25, 39).)

[12] Plaintiffs argue that on December 26, 2018, Ross Gencheff, the Smiths Medical Product Manager responsible for cartridges, and his boss, Jeffrey Hohn, discussed the cartridge restrictions with Beth Rhodes, UTC's VP of Global Supply Chain, and UTC President Michael Benkowitz. (ECF No. 106-1 at 16 (citing Ex. 474 (ECF No. 112-28) at 74; Gencheff Dep. (ECF No. 137-10) at 263:6-264:10).) Less than two hours later, Plaintiffs contend, Hohn emailed, "[W]e have a contract amendments [sic] from UTC that requires us to only sell to MS3 [sic] cartridges to UTC designated customers . . . . [It] is very important to UTC to prevent generic drug users . . . ." (ECF No. 106-1 at 16 (citing Ex. 475 (ECF No. 112-28) at 78).)

claim those agreements always contemplated exclusivity, which is apparent, for instance, in a review of the language of the Second Amendment.[13]

"Anticompetitive effect has been described as a reduction in output, increase in price, or deterioration of quality of goods and services." *Wallace*, 2005 WL 3239208, at *3. Here, the Smiths Medical-UTC supply agreements increased the output of cartridges, production of which otherwise would have ended in 2018, though the Smiths Medical agreements with the specialty pharmacies limited that supply to UTC users. Plaintiffs argue prices in the treprostinil market are artificially inflated, but this is based on data showing not that prices have risen but rather that prices have not fallen as much as would otherwise be expected in the wake of generic entry into a market. Finally, there is no allegation about any deterioration of quality of goods and services.

Defendants further contend the exclusive pump and cartridge agreements not only are not anticompetitive, but instead are procompetitive because they prevent other companies from free riding off UTC's supply. Free riding, UTC argues, discourages innovation and diligent business planning. (ECF No. 122 at 32 (citing *Business Electronics*, 485 U.S. at 724–25; *GTE Sylvania*, 433 U.S. at 55 (finding that manufacturers may restrict distributors to combat the "'free rider' effect")).) Essentially, UTC argues the agreements are procompetitive because the finite supply of available cartridges should have prompted Plaintiffs either to develop a rival pump system,[14]

[13] Section 6 of the Second Amendment provides that Smiths Medical "shall use its commercially reasonable efforts to sell Cartridges to SM Customers and to UT Customers in the ordinary course of its business" while UTC "shall purchase and take title to all unsold, unexpired Cartridges" at the end of the contract. (ECF No. 131 ¶ 13, Ex. 67 (CADD MS® 3 Pump Supply Agreement).) Section 7 provides: "In order to ensure supply is available for use in connection with Remodulin® drug product, Smiths Medical and [UTC] agree that Product shall only be sold" to UTC and certain approved parties, including the specialty pharmacies Accredo and CVS Specialty. (*Id.*)

[14] Defendants stated at oral argument that UTC used the MiniMed Paradign pump from Remodulin®'s launch in 2002 through the 2006 debut of the CADD-MS® 3. (ECF No. 162 at

expanding the choice of drug-delivery systems available to consumers, or to find its own way of accessing a supply of cartridges, which would increase the supply of cartridges available not just for Plaintiffs' patients, but also for other uses, such as the 88,000-order from one of the specialty pharmacies for an antinausea drug.[15]

The Court is persuaded Defendants have presented a procompetition rationale for the challenged agreements and thus have met their burden under *American Express*.

RareGen claimed at oral argument that it had no notice of the finite supply of cartridges until it was told by one specialty pharmacy in late 2018 that cartridges would not be available because UTC controlled them. However, UTC has presented evidence Sandoz was aware or should have been aware of CADD-MS® 3 problems as early as May 2016, when Smiths Medical told a Sandoz executive it wasn't selling the pumps anymore (ECF No. 131-1, Ex. 5, Zhu 5-17-2016 email), or in early 2017, when Sandoz learned cartridges no longer were on a Smiths Medical list of available accessories (ECF No. 131-4, Exs. 20 (Bernard O'Callahan 2/24/2017 email); ECF No. 131-5, Ex. 21 (Flynn 3/2/2017 email)), or in January 2019, before Sandoz's March 2019 launch, when one specialty pharmacy confirmed cartridges were available only for Remodulin® patients. (ECF No. 132-17, Ex. 605; ECF No. 132-18, Ex. 606; ECF No. 132-19, Ex. 607 (Texts of Internal Sandoz Chats).) The Court also is persuaded by UTC's argument that Sandoz could have attempted to obtain clearance in the U.S. for pumps currently being used overseas, including the MiniMed Paradign, the pump UTC used from 2002 to 2006, when the CADD-MS® 3 was launched. (ECF

39:15-16.) Defendants further stated that this pump is being used in other countries and "could be cleared [by the FDA] again for use in this country." (*Id.* at 39:18-20.)

[15] (*See* ECF No. 122 at 9 (citing Exs. 89 (ECF No. 131-17), 1074 (ECF No. 132-46)).)

No. 132-48, Ex. 1076 (5-28-2018 Letter to Federal Trade Commission at 2-3); ECF No. 133-9, Ex. 1104 (Attachments to Benkowitz 12-7-2017 email).)

Having concluded Defendants have presented a procompetition rationale for the challenged restraints, the burden shifts back to Plaintiffs to demonstrate the procompetitive efficiencies were pretextual or could have been reasonably achieved through less anticompetitive means. *See Am. Express*, 138 S. Ct. at 2284 (setting forth step three).

Plaintiffs argue these justifications are pretextual because there is no evidence the restraints on cartridge sales were needed to expand cartridge sales because the output expansion occurred under the 2016 and 2017 agreements, well before the 2019 restraints on non-Remodulin® uses were established. (ECF No. 106-1 at 32.) Furthermore, Plaintiffs contend, there is no evidence the restraints were necessary to expand Smiths Medical's capacity to make cartridges or that UTC would not have committed to buy the cartridges without the restraints. Finally, Plaintiffs argue since Smiths Medical has enough resin on hand to make cartridges through 2026, there is no evidence the restraints were or are necessary to preserve access to cartridges for patients on Remodulin®. (ECF No. 106-1 at 32 (citing Rhodes Dep. (ECF No. 137-17) at 107:1-5, 143:13-144:6; Dep. of Gray (ECF No. 112-3) at 30:9-18, 31:17-25; Dep. of Walker (ECF No. 112-9) at 66:13-16, 128:23-129:5).) And, Plaintiffs say, since UTC plans to move patients off the CADD-MS® 3, "UTC did not need to lock up ***all*** cartridges needed to serve the ***entire*** market through 2026." (*Id.* at 34.)

Even if Defendants' justifications are valid, Plaintiffs argue, there were less-restrictive options available, such as raising prices on the cartridges "to profitably expand its manufacturing capacity" for the cartridges, a product Plaintiffs say generates "hefty profit margins" for Smiths Medical. (*Id.*)

Defendants counter that Plaintiffs' tonic of raising prices in 2016 to "profitably expand [] manufacturing capacity" is counterfactual, unsupported by any evidence and "contrary to [Smiths Medical's] analysis that it maximized profits by discontinuing the CADD-MS® 3 and focusing on other products." (ECF No. 122 at 34 (citing Decl. of Chris Quinn, Chief Technical Engineer for the Infusion Business at Smiths Medical (ECF No. 127) ¶¶ 6–9, 15; Stamp Decl. (ECF No. 128) ¶ 7).) Instead, Defendants contend, "UTC ultimately funded production of a ten-year supply of cartridges to match the useful life of its pumps; as it became possible for Smiths to manufacture additional cartridges, UTC agreed to underwrite the additional output." (*Id.* (citing Rhodes Dec. (ECF No. 126) ¶¶ 6, 8, 12).)

The Court is not persuaded that Defendants justifications were pretexual, or that Defendants had less-restrictive means of increasing supply of cartridges when the original agreement was struck in 2016. Based on evidence from the limited discovery conducted for the Preliminary Injunction Motion, it appears Smiths Medical presented to UTC "a business reality . . . that dictated a response." (ECF No. 122 at 4-5 (citing Dep. of Roger Andrew Jeffs, former President and Chief Operating Officer for UTC (ECF No. 112-11) at 102:12–104:13, 107:14–18).) That reality was discontinuation of the only pumps relied on by patients using its Remodulin® and a supply of only roughly three years of the cartridges required to use those pumps. UTC responded by funding continued production of a product line Smiths Medical had concluded was "increasingly expensive" to produce and for which it was outstripping the supply of FDA-cleared parts. (*Id.*) There is no evidence any other company funded continued production of the pumps or cartridges, though there is evidence other companies also used these cartridges. Also, Plaintiffs have not explained how the restraints contained in the 2019 Agreement they say were intended to

block Plaintiffs' entry into the market were being enforced by the specialty pharmacies in late 2018.

The *American Express* burden-shifting procedure involves close factual analysis to determine whether a restraint violates the rule of reason. Plaintiffs met their burden of demonstrating the restraints had an anticompetitive effect, while Defendants met their burden of showing a procompetition rationale for the restraints. However, the Court is not persuaded Plaintiffs met their burden of showing Defendants could have employed less anticompetitive means. As a result, the Court concludes Plaintiffs have not met their burden of demonstrating a reasonable probability of eventual success in the litigation as required by *Reilly* and thus this prong weighs against granting the Motion to permanently enjoin Defendants from enforcing the exclusive cartridge-supply agreements.

b. Irreparable Harm

To warrant the issuance of an injunction, "[a] plaintiff has the burden of proving a clear showing of immediate irreparable injury." *Hoxworth v. Blinder, Robinson & Co.*, 903 F.2d 186, 205 (3d Cir. 1990) (internal quotations omitted). Furthermore, the plaintiff must demonstrate a nexus between that injury and the alleged anticompetitive behavior of defendants. *Van Dyk Research Corp. v. Xerox Corp.*, 631 F.2d 251 (3d Cir. 1980).

The Clayton Act establishes the standard under which a business may recover for an anticompetitive injury. Pursuant to § 4, Sandoz must prove three essential elements: 1) an unlawful conspiracy among defendants in restraint of trade; 2) an anticompetitive injury proximately caused by defendants' illegal conduct; and 3) the measurable damages plaintiff has sustained. *American Bearing Co. v. Litton Indus.*, 729 F.2d 943, 948 (3d Cir. 1984).

Plaintiffs allege Defendants conspired to suppress generic competition, thus reducing consumer choice. From this, Plaintiffs argue they have suffered irreparable injury to their reputation in the marketplace from which they will not recover, and that they are suffering from now and will continue to suffer from their inability to gain a toehold in this market. (ECF No. 106-1 at 36.) This reputational harm, Plaintiffs claim, cannot be easily quantified or addressed with money damages, and is a continuing injury requiring an injunction. (*Id.*) Plaintiffs cite *Byrne v. Calastro* for the proposition that reputation and image constitute irreparable for preliminary injunction purposes. 205 F. App'x 10, 16 (3d Cir. 2006).

Defendants counter that Plaintiffs' assertions are speculative and factually unsupported by any evidence beyond the statement of Plaintiffs' own economist that the company believes reputational harm is occurring and statements by the companies themselves, thus lacking the "clear showing" required in the Third Circuit. (ECF No. 122 at 19 (citing Rao Rpt. (ECF No. 109) ¶ 104, deGoa Aff. (ECF No. 108) ¶ 39, and *ECRI v. McGraw-Hill, Inc.*, 809 F.2d 223, 226 (3d Cir. 1987)).) Furthermore, any harm experienced by Plaintiffs is self-inflicted, based on their choice to launch their product knowing there was no supply of cartridges for administering their drug. (*Id.*) Defendants also point to a statement by RareGen's CEO that any reputational harm "will persist even if the cartridge restrictions go away." (*Id.* at 22 (citing deGoa Aff. (ECF No. 108) ¶ 40).) In any event, Defendants argue, even if Plaintiffs could provide evidence, any harm would be compensable by money damages. (*Id.*) Either way, Defendants say, Plaintiffs have not carried the burden justifying a preliminary injunction.

The Court is aware of *Byrne*. Still, the Court agrees with Defendants that to the extent injury is proved at trial, damages would be calculable. Indeed, at oral argument Plaintiffs referred to a table from the report of their economist portraying how the demand curve shifts monthly to

the generic version in the year following launch of the generic. (ECF No. 162 at 45:6-10 (citing Plaintiffs' Slide 11 (citing Rao Report (ECF No. 109) at Tab 6).) Certainly such calculus could be augmented with price differentials to reach a total damages calculation. Also, while the *Byrne* court determined harm to reputation and image can be sufficient for preliminary injunction purposes, this unpublished opinion does not require it. Furthermore, the Court observes that *Byrne* is distinguishable from the matter at hand by the allegations there of financial irresponsibility, the wasting of assets, and a criminal investigation. These elements are lacking in the matter before this Court. Therefore, the Court concludes Plaintiffs have not carried their burden of demonstrating with sufficient clarity irreparable harm. This factor also weighs against granting the Motion.

As a general proposition, the conclusions that Plaintiffs failed to demonstrate a reasonable probability of eventual success in the litigation and failed to evidence irreparable harm would end the Court's inquiry. As the Third Circuit stated in *Reilly*, "[t]he first two factors are the 'most critical.'" *Reilly*, 858 F.3d at 179. Only if those factors are met should a Court proceed to factors three (balance of the equities) and four (public interest), and then "determine[] in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief." *Id.* at 179.

Plaintiffs, however, averred at oral argument that in this litigation the public-interest factor is paramount, because "the public interest is in having access to all of the competing drugs . . . in being able to choose between the Remodulin® product and Plaintiffs' generic product." (Hearing Tr., ECF No. 162 at 18:17-24.) However, the Court is not persuaded it should stray from the standard reaffirmed by the Court in *Reilly*. Having determined Plaintiffs have not met their burdens of showing a reasonable probability of eventual success in the litigation or demonstrated irreparable harm, the Court is unwilling to ignore what *Reilly* teaches about the importance of the

first two prongs. As a result, the Court concludes the Preliminary Injunction Motion is denied as to Plaintiffs' § 1 claim.[16]

2. § 2 Antitrust Claim

The reasonable-probability-of-eventual-success prong of the *Reilly* test now requires this Court to determine whether Plaintiffs are likely to succeed on the merits of their § 2 claim.

Plaintiffs claim Defendants' restrictions on the sale of cartridges have enabled UTC to maintain a monopoly over a large segment of the relevant market "that it does not deserve and has not earned." (ECF No. 1 ¶ 50.) To prevail on a § 2 claim, Plaintiffs must prove Defendants possess monopoly power in the relevant market and the "willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Queen City Pizza*, 124 F.3d at 437(citing *Aspen Skiing*, 472 U.S. at 596 n.19 (quoting *Grinnell Corp.*, 384 U.S. at 570–71)).)

Monopoly power is the power to control prices or exclude competition. *U. S. v. E. I. du Pont de Nemours & Co.*, 351 U.S. 377, 389, 76 S. Ct. 994 (1956). It is clear UTC has monopoly power over the market for treprostinil because UTC's Remodulin® was the only treprostinil drug on the market before the launch of Sandoz's generic version and because, if Sandoz has been unable to enter the subcutaneous market, it still was the only drug on that market at the instigation of this litigation.

[16] Though the Court concludes Plaintiffs have not met their burden of showing a reasonable probability of success on the merits for the purposes of the Motion for a Preliminary Injunction, this finding does not preclude a finding in Plaintiffs' favor on the Motion to Dismiss, as discussed below.

Thus, the Court next must determine whether UTC maintained that power through means other than from "growth or development as a consequence of a superior product, business acumen, or historic accident." *Grinnell*, 384 U.S. at 571.

Plaintiffs attribute UTC's continued dominance to illegal restraints, which suddenly appeared only as Sandoz was preparing to launch its generic treprostinil. Defendants argue their business acumen spurred UTC to a reasonable and rational response to the "business reality" of the swift termination of the drug-delivery system used by patients prescribed UTC's Remodulin®, while Plaintiffs failed to respond to repeated signals of CADD MS3 troubles.

The Court is persuaded from the wording of the original 2016 Pump Supply Agreement that UTC's concern was not keeping Sandoz out of the market for treprostinil, but rather with ensuring continuity of supplies of pumps and cartridges for its customers at a time when there were no other treprostinil competitor, and that the exclusive nature of this production agreement was contemplated from inception. This can be seen in part in the fact that the 2016 and 2017 agreements reserved to Smiths Medical only a small portion of the manufacturing run of pumps and cartridges being financed by UTC's investment. Plaintiffs at oral argument conceded UTC owns the cartridges. (ECF No. 162 at 17:22-23.) In other words, UTC owns the cartridges because it bought the lion's share of the production runs in 2016-2018, well before Sandoz entered the market. And, Sandoz has produced no evidence UTC's purchase of that lion's share was motivated by or intended to forestall Sandoz's entry into the subcutaneous market. The Court is further persuaded that the exclusivity that is more explicit in the 2019 Agreements' restraints was a response as much to reports that the run rate of cartridges was exceeding projections because the specialty pharmacies were selling the cartridges for uses other than Remodulin® as it was to the prospect that the launch of generic treprostinil would further accelerate that run rate of cartridges.

The Court concludes Plaintiffs have not met their burden of showing a reasonable probability of eventual success on their § 2 claim. Thus, this prong weighs against granting the Motion and against permanently enjoining Defendants from enforcing the exclusive cartridge-supply agreements. The Court further concludes the irreparable harm analysis conducted for the § 1 claim governs for the § 2 claim.

Because Plaintiffs have not met the burden of showing either a reasonable probability of eventual success on the merits nor irreparable harm on their § 2 claim, pursuant to *Reilly* the Court concludes the Motion is denied as to Plaintiffs' § 2 claim.[17]

3. Motion to Dismiss

Defendants argue the claims under the Antitrust Act's §§ 1 and 2 should be dismissed because Plaintiffs have not pleaded that they were substantially foreclosed from the market and have not pleaded facts supporting a plausible inference that UTC's and Smiths's actions were anticompetitive. (Defs.' Br. (ECF No. 53-1) at 1.) Defendants further argue three of Plaintiffs' state-law claims duplicate Plaintiffs' antitrust claims, and thus fail along with them, while the fourth state-law claim fails because Defendants' actions were commercially reasonable and thus are privileged under applicable law. (*Id.*)

Plaintiffs counter that the Complaint alleges sufficient facts showing "Defendants' unlawful restrictions have entirely foreclosed" the market for subcutaneously injected treprostinil and have foreclosed about 40% of the market for injected prostacyclin. (ECF No. 56 at 2 (citing ECF No. 1 ¶¶ 72, 74.) Plaintiffs also contend that in addition to exclusive dealing, the Complaint describes Defendants' unlawful tying arrangements and their conspiracy to monopolize at least

[17] As stated in n.16 supra, this finding does not preclude a finding in Plaintiffs' favor on the Motion to Dismiss, as discussed below.

two relevant antitrust markets. (*Id.*) Finally, Plaintiffs deny the state-law claims are duplicative of the Antitrust Act claims, arguing that they are distinct claims with different elements and different standards of proof than federal and state antitrust claims. (ECF No. 56 at 3.) Furthermore, Plaintiffs contend, "Defendants have failed to show that their arguments concerning foreclosure, competitive harm, and antitrust injury would dispose of those claims under applicable state law." (*Id.*)

To prevail on a § 1 claim, Plaintiffs must prove "(1) concerted action by the defendants; (2) that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted action was illegal; and (4) that the plaintiff was injured as a proximate result of the concerted action." *Queen City Pizza*, 124 F.3d at 442 (citing *Mathews v. Lancaster General Hospital*, 87 F.3d at 639; *Orson v. Miramax Film*, 79 F.3d at 1366; *Petruzzi's IGA Supermarkets*, 998 F.2d at 1229).

To prevail on their § 2 allegation, Plaintiffs must show Defendants (1) possess monopoly power in the relevant market and (2) willfully maintained or acquired that power "as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Aspen Skiing*, 472 U.S. at 596 n.19 (quoting *Grinnell*, 384 U.S. at 570–71).

Count 3's restraint-of-trade claim pursuant to N.J. Stat. Ann. § 56:9-3 closely tracks federal Antitrust jurisprudence for § 1. *Kugler v. Koscot Interplanetary, Inc.*, 293 A.2d 682 (N.J. Super. Ch. Div. 1972).

For Count 4, under N.C. Gen. Stat. § 75–1.1, which forbids unfair and deceptive trade practices, law, Plaintiffs must show "an adverse effect on competition when the claim is directed at anticompetitive (rather than unfair or deceptive) practices." *Sewell Plastics, Inc. v. Coca-Cola Co.*, 720 F. Supp. 1196, 1220 (W.D.N.C. 1989) (citing *Chuck's Feed & Seed Co., Inc. v. Ralston Purina Co.*, 810 F.2d 1289, 1295–96 (4th Cir. 1989)).

For Count 5, under North Carolina law Plaintiffs must show: (1) defendants committed an unfair or deceptive act or practice; (2) in or affecting commerce; and (3) that plaintiff was injured thereby. *First Atlantic Management Corp. v. Dunlea Realty Co.*, 507 S.E.2d 56, 63, 131 N.C. App. 242, 252 (N.C. App. 1998) (citing *Canady v. Mann*, 107 N.C. App. 252, 260, 419 S.E.2d 597, 602 (1992); N.C.G.S. § 75–1.1 (1994).) Plaintiffs also must show they "suffered actual injury as a proximate result of defendants' misrepresentations" or unfair conduct. *First Atlantic Management Corp. v. Dunlea Realty Co.*, 507 S.E.2d 56, 63, 131 N.C. App. 242, 252 (N.C. App. 1998) (citing *Ellis v. Smith–Broadhurst, Inc.*, 48 N.C. App. 180, 184, 268 S.E.2d 271, 273–74 (1980); N.C.G.S. § 75–16 (1994).

For Count 6, a plaintiff "must demonstrate that a plaintiff was in 'pursuit' of business, that the interference complained of was done intentionally and with "malice." *Printing Mart-Morristown v. Sharp Electronics Corp.*, 563 A.2d 31, 37, 116 N.J. 739, 751 (1989) (citations omitted).

While a preliminary injunction is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief," *Winter v. Natural Res. Def. Council*, 129 S. Ct. 365, 376 (2008), in a Motion to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a Plaintiff's Complaint merely "must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 570). The Court concluded for the purposes of the Preliminary Injunction Motion that Plaintiffs had met their burden of demonstrating concerted action by Defendants and that the restraints had an anticompetitive effect, meeting the first and second elements of a § 1 claim as elucidated by *Queen City Pizza*, 124 F. 3d at 442. However, the failure of Plaintiffs to show immediate irreparable injury as required by *Blinder Robinson* for a

preliminary injunction does not negate this Court's conclusion that Plaintiffs have met the lower 12(b)(6) standard of plausibly pleading facts evidencing that the concerted action of Defendants was illegal and that the Plaintiffs were injured as a proximate result of the concerted action. (*Id.*)

Similarly, the Court observed above that Defendants possess monopoly power in the treprostinil markets and the Court concludes Plaintiffs have plausibly pleaded facts to allow the reasonable inference that Defendants willfully maintained or acquired that power in manners prescribed by § 2. *See Aspen Skiing,* 472 U.S. at 596 n.19 (quoting *Grinnell,* 384 U.S. at 570–71).

As to the state-law claims based on North Carolina statutes, it is well established in North Carolina and in the Fourth Circuit that "the federal antitrust laws do not preempt the states from regulating unfair business practices." *American Rockwool, Inc. v. Owens-Corning Fiberglas Corp.*, 640 F. Supp. 1411, 1428 (E.D.N.C. 1986). In addition, *Itco Corp. v. Michelin Tire Corp., Comm. Div.*, stands for the proposition "proof of conduct violative of the Sherman Act is proof sufficient to establish a violation of the North Carolina Unfair Trade Practices Act." 722 F.2d 42, 48 (C.A.N.C. 1983). North Carolina's stance echoes that of New Jersey. *See Glasofer Motors v. Osterlund, Inc.*, 433 A.2d 780, 788 (N.J. Super. App. Div. 1981) (citing *State v Lawn King,* 417 A.2d 1025 (1980).

As the proofs required for the state-law claims parallel those for the Antitrust Act claims and the Court has concluded Plaintiffs' pleading meets the Rule 12(b)(6) burden for §§ 1 and 2 claims, it is axiomatic Plaintiffs' state-law claims also meet the Rule 12(b)(6) standard. Accordingly, Defendants' Motion to Dismiss the Complaint is **DENIED.**

IV. CONCLUSION

For the reasons set forth above, Plaintiffs' Motion for a Preliminary Injunction (ECF No. 106) is **DENIED**, while Defendants' Motion to Dismiss (ECF No. 53) also is **DENIED.** An appropriate order will follow.

Date: January 29, 2020

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE